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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/338,730 11/14/94 WEISS

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EXAMINER

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18N2/1001

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ART UNIT

PAPER NUMBER

1804

9

DATE MAILED: 1994

10/01/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

10/01/96

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/8/96

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

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This application should be reviewed for errors.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10 are active and examined in this Office Action.

The provisional rejection of claims 1-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of 08/270,412, 08/376,062, 08/359,945 is maintained in view of the lack of a terminal disclaimer or amendments to the claims clearly delineating the metes and bounds between the inventions in the applications.

The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, is maintained. The amendments to the claims regarding the phrase "and/or" do not clarify the meaning of the claim. Applicant's arguments, filed July 1996, have been considered but not found to be persuasive. Applicants have argued that they intend to distinguish between proliferative factors and regulatory factors; however, the ability to distinguish between the two outcomes is not easily applied to the use of growth factors. The art does not teach that each factor has one and only one activity and the attempt to claim solely one effect or the other is not biologically possible.

The rejection of claims 1-8 under 35 U.S.C 103 as being unpatentable over Boss taken with Anchan, Lin, Ferrari and Morshead is maintained. Applicants have argued that Boss fails to disclose that multipotent neural stem cells were induced to proliferate as required by claim 1. However, Boss discloses that the progenitor cells differentiated and, lacking evidence to the contrary, the cells of Boss may have been induced to proliferate. Applicants' assertions that the cells of Boss did not proliferate are unsupported. Note that by selecting for neuronal progenitor cells, applicants have selected for the cells produced by the stem cells, and therefore the stem cells have proliferated.

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Applicants have argued that the references portion of Anchan does not concern neural stem cell proliferation; that it describes primary cultures of embryonic and neonatal retinal cells and concludes that many of the cells are actively dividing in the cultures are neural progenitors, and that neuronal progenitor cell is not a multipotent neural stem cell. However, claim 1 allows for the regulation of precursor cells derived from multipotent neural stem cells and this is taught by Anchan and Boss.

Applicants have argued that the cell cultured by Anchan did not produce progeny which differentiated into neurons, astrocytes and oligodendrocytes. However, no current claim claims that limitation.

Applicants have argued that with respect to claim 3, that mere survival is not the same as proliferation. However, claim 1, from which claim 3 depends, does not require that the factor be applied to neural stem cells as claim 1 also permits "regulation of the proliferation" and clearly factors permitting survival also regulate the proliferation. Ferrari also discloses that bFGF promotes survival and "development of neurons" in cultures and neurons "develop" from less developed cells thereby fulfilling the requirement of regulation of proliferation.

Applicants have stated that it is unclear how the first sentence of the middle paragraph on page 5 of the office action relates to the claims of the present application. Applicants are reminded that the motivation to add any growth factor is to produce cells having particular desired characteristics. The specification discloses that neurodegenerative disorders such as Parkinson's are a leading source of CNS dysfunctions, that treatment using cells removed from the patient and cultured to compensate as replacement cells would be desirable. Therefore, in view of the fact that claim 10 removes the cells from a patient

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having a neurodegenerative disease and the specification discloses use of the cells as a treatment, the meaning of claims 5 and 10 have been examined in light of the specification. The motivation for adding growth factors is to produce a population of cells having a certain lineage and which would be useful for application to neurodegenerative diseases.

Applicants have argued that the examiner stated that the use of heparin sulfate is obvious over the use of other growth factors since the specification discloses that heparin sulfate promotes binding of bFGF to its cell surface receptor. However, while the specification location of such a statement cannot be determined, and the use of heparin sulfate is obvious over the use of the other growth factors.

Applicants have argued that claim 6 depends from claim 3 and that therefore claim 6 requires a combination. However, such an interpretation has never been given to that claim by the examiner; if a combination was claimed, then the claim should have read "The method of claim 3, further comprising the addition growth factor, said growth factor being EGF" or some other such language. Applicants' arguments regarding this claim and the combination interpretation are moot. Claim 6, as currently written, does not require a combination.

Regarding claim 8, applicants have argued that one would not have modified the method of Boss by using the adult tissue studies by Morshead because it would not be expected that the modification would result in the proliferation of dopaminergic cells. However, the claims do not claim any particular type of tissue and Morshead was cited to disclose the presence of neural stem cells. Further to applicant's arguments, stem cells are stem cells and once a composition containing stem cells has been identified as in Morshead, the cells are capable of differentiating and proliferating.

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The rejection of claims 9 and 10 under 35 U.S.C. 103 as being unpatentable over Boss, Anchan, Lin, Morshead and Ferrari as applied to claims 1-8 above and further in view of Gage is maintained. Applicants have argued that Gage does not suggest that it was possible to proliferate human multipotent neural stem cells in culture. However, Boss, Anchan, Lin, Morshead and Ferrari were cited to teach proliferation. Gage was cited to disclose the use of autologous cells and to teach the method of transplanting cells to treat neurodegenerative diseases.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO FAX center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (30 November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-0294.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Suzanne Ziska, Ph.D., whose telephone number is (703)308-1217. In the event the examiner is not available, the examiner's

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supervisor, Ms. Jacqueline Stone, may be contacted at phone number (703) 308-3153.


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GROUP 1800